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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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TRADILICAIN

Morton, et al.

App. No.

10/072,543

Filed

February 8, 2002

For

DISPOSABLE FLUID LOOP

FOR INTRADUCTAL FLUID

ASPIRATION SYSTEM

Examiner

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Group Art Unit 1645

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Dear Sir:

Enclosed is form PTO-1449 listing 138 references. These references were previously disclosed to the Patent and Trademark Office in the prosecution of U.S. 09/870,402, filed May 30, 2001, which is the parent of this application. This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required in accordance with 37 C.F.R. § 1.97(b)(3). If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated.

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Rose M. Thiessen, Attorney of Record

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FORM PTO-1449

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APPLICATION NO. ⁻ 10/072,543

INFORMATION DISCLOSURE STATEMENT

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ERAL SHEETS IF NECESSARY)

			U.S. PATENT DOCUMENTS			
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	09/488,893	1/21/00	Covington, et al			
	09/488,905	1/21/00	Chandice Covington			
	20010034038 A1	10/25/01	Hung, D.			
	20010039015 A1	11/8/01	Sauter, E.			IEN
	20020002343 A1	1/3/02	Hung, et al.	Q.	ECE	AL
	20020007115 A1	1/17/02	Hung, et al.	100	20 NY 1	e 5005
	20020010405 A1	1/24/02	Hung, et al.		- WHAT	EH 1600 5800 6 5005 AED
	20020013539 A1	1/31/02	Hung, D.		CH CENT	ER 1800
	3,608,540	09/1971	Sartorius	NE.	 	
	3,786,801	01/1974	Sartorius			
	3,822,703	07/09/74	Davisson			COPY OF PAPER ORIGINALLY FILE
	4,249,481	02/10/81	Adams			OURINALIA EILE
	4,393,811	07/19/83	Bodmin			
	4,452,779	06/05/84	Cockerill			
	4,542,750	09/1985	Ettare			
	4,680,028	07/14/87	Stuart			
	4,761,160	08/02/88	Vermillion			
	4,883,464	11/28/89	Morifuki			
	4,941,433	07/17/90	Hanauer			
	4,964,851	10/23/90	Larsson			
	5,007,899	04/16/91	Larsson			
	5,049,126	09/17/91	Larsson			-
	5,476,492	12/19/95	Unrug			
	5,482,004	01/09/96	Chowdhury			
	5,493,995	02/27/96	Chowdhurry			

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ORIGINALLY FILED **U.S. PATENT DOCUMENTS EXAMINER** DOCUMENT NUMBER DATE NAME CLASS SUBCLASS FILING DATE INITIAL (IF APPROPRIATE) 5,576,329 11/19/96 Hennessey 05/1997 5,627,034 Gould et al. 5,645,537 07/08/97 Powles et al. BECHCENTER 1600/2900 5,664,984 09/09/97 Laughridge 5,720,722 02/24/98 Lockridge 5,741,649 04/21/98 Inazawa 5,776,098 07/07/98 Silver et al. 07/07/98 MacWhinnie et al. 5,776,177 08/25/98 5,797,875 Silver 5,798,266 08/1998 Quay et al. 09/22/98 5,810,796 Kimura et al. 5,846,739 12/1998 Gould et al. 01/05/99 5,855,889 Watson, et al. 03/23/99 5,885,246 Ford 04/1999 Khalkhali 5,895,640 05/1999 5,902,267 Medo 5,902,279 05/11/99 Powles et al. 5,913,686 06/1999 Van Winkle 5,914,238 06/1999 Keesee et al. 5,922,836 07/13/99 Watson, et al. 5,941,847 08/24/99 Huber et al. 6,004,186 12/21/99 Penny 6,004,756 12/21/99 Watson et al. 6,063,029 05/16/00 Saita et al. 08/29/00 6,110,140 Silver

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			U.S. PATENT DOCUMENTS		·-	
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	6,287,521 B1	09/11/01	Quay, et al.			
	6,314,315 B1	11/6/01	Hung, D.			
	6,316,189 B1	11/13/01	Haddad, et al.			
	6,316,215 B1	11/13/01	Adair, et al.			

			FOREIGN	PATENT DOCUMENTS				
EXAMINER	DOCUMENT NUMBER	DATE		COUNTRY	CLASS	SUBCLASS	TRANS	LATION
INITIAL	WO 98/22160	05/28/98	PCT				YES	NO

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	Adami et al., "Absence of association between reproductive variables and the risk of breast cancer in young women in Sweden and Norway," British Journal of Cancer, Vol. 62, pp. 122-126 1990.
	America Cancer Society Cancer facts and figures, 1996.
	American Cancer Society Breast cancer facts and figures, 1996.
	Anderson et al., <u>Cancer</u> , Vol. 65, 1901-1908 1989.
	Basu et al., "Serum vitamins A and E, beta-carotene, and selenium in patients with breast cancer," Journal of the American College of Nutrition, Vol. 8, pp. 524-529 1989.
	Bendich et al., "Antioxidant nutrients and immune function," Advances in Experimental Medicine and Biology, Vol. 262, New York: Plenum Press 1990.
	Brisson et al., "Diet, mammographic features of breast tissue, and breast cancer risk," American Journal of Epidemiology, Vol. 130, pp. 14-24 1989.
	Britton et al., Carotenoids Vol. 1a: Isolation and analysis. Basel: Birkhausen Verlag 1995.
	Burton et al., "Antioxidant action of carotenoids," Journal of Nutrition, Vol. 119, pp. 109-115 1989.
	Burton et al., "Beta-carotene: An unusual type of lipid antioxidant," Science, Vol. 224, pp. 569 1984.
	Byers et al., "Dietary carotenes, vitamin C, and vitamin E as protective antioxidants in human cancers," Annual Review of Nutrition, Vol. 12, pp. 139-159 1992.
	Byers et al., "Lactation and breast cancer," American Journal of Epidemiology, Vol. 121, pp. 139-159 1985.
	Dawood et al., American Journal of Obstetrics and Gynecology, , 138, 20-24, 1980
	DeLuca, "Vitamin A" In: The fat-soluble vitamins, H. Deluca (Ed.), pp. 1-67, New York; Plenum Press. 1978.

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DATE CONSIDERED

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. NEOMTRX.4C1DV2

APPLICATION NO. 10/072,543

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FILING DATE 02/08/2002 GROUP 1645

TECH CENTER 1600/2900

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)						
	Di Mascio et al., "Antioxidant defense systems: The role of carotenoids, tocopherols, and thiols," American Journal of Clinical Nutrition, Vol. 53, pp. 194-200 1991.						
	Ewertz et al., "Dietary factors and breast-cancer risk in Denmark," International Journal of Cancer, Vol. 46, pp. 779-784 1990.						
•	Gaitan et al., Endocrinology, Sep, S1(3), 515-520, 1967.						
	Greiner Pharmaceutical Tech., May 1993, pp. 28-44 1993.						
	Haagensen et al., <u>Breast carcinoma: Risk and detection</u> , Philadelphia: W.B. Saunders Company 1981. Hill et al., "Retinoids and Cancer Prevention," <u>Annu. Rev. Nutr.</u> Vol. 12, pp. 161-181 1992.						
	Hislop et al., "Diet and histologic types of benign breast disease defined by subsequent risk of breast cancer," American Journal of Epidemiology, Vol. 131, pp. 263-270 1990.						
£0	Holmes et al., "Dietary guidelines," In: Reducing breast cancer in women, B. Stoll (Ed.), pp. 135-144 1995.						
	Inaji et al., <u>Cancer</u> Vol. 60, 3008-3013 1987.						
Ē	Ing et al., "Unilateral breast feeding and breast cancer," The Lancet, Vol. 7, pp. 124-127 1977.						
ALLY FILED	Katsouyanni et al., "Risk of breast cancer among Greek women in relation to nutrition intake," Cancer, Vol. 61, pp. 181-185 1988.						
I	Kinsel et al., <u>Cancer Res</u> . 49: 1052-1056, 1989.						
/	Knecht et al., "Serum vitamin A and subsequent risk of cancer: Cancer incidence follow-up of the finish mobile clinic health examination survey," American Journal of Epidemiology, Vol. 132, pp. 857-870 1990.						
	Krinsky et al., "Interaction of oxygen and oxy-radicals with carotenoids," Journal of the National Cancer Institute, Vol. 69, pp. 205 1982.						
	Krinsky, "Actions of Carotenoids in Biological Systems," Annu. Rev. Nutr, Vol. 13, pp. 561-587 1993.						
	Kvale et al., "Lactation and cancer risk: Is there a relationship specific to breast cancer," Journal of Epidemiology and Community Health, Vol. 42, pp. 30-37 1987.						
	Layde et al., "The independent association of parity, age at first full-term pregnancy, and duration of breastfeeding with the risk of breast cancer," Journal of Clinical Epidemiology, Vol. 42, pp. 963-973 1988.						
	Levin et al., "Lactation and menstrual function as related to cancer of the breast," American Journal of Public Health, Vol. 54, pp. 580 1964.						
	Love, "Introduction" In: Reducing breast cancer risk in women, B. Stoll (Ed.), 1995.						
	Lubin et al., "Risk factors for breast cancer in women in Northern Alberta Canada as related to age at diagnosis," Journal of the National Cancer Institute, Vol. 68, pp. 211-217 1992.						
	MacMahon et al., "Lactation and cancer of the breast: a summary of an international study," Bulletin of the World Health Organization, Vol. 42, pp. 85 1970.						
	Marubini et al., "The relationship of dietary intake and serum levels of retinol and beta-carotene with breast cancer," Cancer, Vol. 61, pp. 173-180 1988.						
	Matthews-Roth, Curr. Top. Nutr. Dis. (New Prot. Roles Select Nutr.) Vol. 22, pp. 17-38 1989.						
	Matthews-Roth, Pure Appl. Chem. Vol. 57, pp. 717-722 1985.						

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DATE CONSIDERED

*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

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APPLICATION NO. 10/072,543

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APPLICANT Morton, et al.

MAY 1 6 2002

FILING DATE 02/08/2002 GROUP TECH CENTER 1600/2900

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	McTiernan et al., "Evidence of a protective effort of lactation on risk of breast cancer in young women," American Journal of Epidemiology, 124, 353-358, 1986.
	Michnovicz et al., How to reduce your risk of breast cancer., New York: Warner Books 1994.
•	Mori et al., <u>Jpn. J. Clin. Oncol</u> . 19: 373-379 1989.
	Murrell, "Epidemiological and biochemical support for a theory on the cause and prevention of breast cancer," Medical Hypotehses, 36, 389-396, 1991.
	Negri et al., "Intake of selected micronutrients and the risk of breast cancer," International Journal of Cancer Vol. 65, pp. 140-144 1995.
80 1	Newcomb et al., "Lactatation and a reduced risk of premenopausal breast cancer," New England Journal of Medicine, Vol. 330, pp. 81-87 1994.
FILE	Paganini-Hill et al., "Vitamin A, beta-carotene, and the risk of cancer: A prospective study," Journal of the National Cancer Institute Vol. 79, pp. 443-448 1987.
ORIGINALLY FILED	Papanicolaou et al., "Exfoliative Cytology of the Human Mammary Gland and Its Value in the Diagnosis of Cancer and Other Diseases of the Breast," Cancer, Vol. 11, No. 2, pp. 377-409, March-April 1958
£	Parl et al., <u>Hum. Pathol</u> . 19: 960-966, 1988.
0	Patton et al. Carotenoids of human colostrums. Lipids. 1990, Vol. 25, No.3, pages 159-165.
	Pertschuk et al., <u>Cancer</u> , Vol. 66, 1663-1670 1990.
	Peto et al., Nature, Vol. 290, pp. 201-208 1981.
	Petrakis et al., "Association of breast fluid coloration with age, ethnicity, and cigarette smoking," Breast Cancer Research and Treatment, Vol. 11, pp. 255-262 1988.
	Petrakis et al., "Association of race, age, menopausal status, and cerumen type with breast fluid secretion in non-lactating women as determined by nipple aspiration," Journal of the National Cancer Institute, Vol. 54, pp. 829-833 1975.
	Petrakis et al., "Cerumen phenotype and proliferative epithelium in breast fluids of U.SBorn immigrant Asian women: A possible genetic-environmental interaction," Breast Cancer Research and Treatment Vol. 16, pp. 279-285 1990.
	Petrakis et al., "Cholesterol and Cholesterol Expoxides in Nipple Aspirates of Human Breast Fluid," Cancer Research, Vol. 41, p.p. 2563-2566, June 1981.
	Petrakis et al., "Correlation of breast fluid related to concentration of cholesterol, cholesterol epoxides, estrogen, and lipid peroxides," American Journal of Clinical Pathology, Vol. 89, pp. 117-120 1988.
	Petrakis et al., "Mutagenic Activity in Nipple Aspirates of Human Breast Fluid", Cancer Research, Vol. 40, 188-189
	Petrakis et al., "Nipple aspirate fluids in adult non-lactating women-lactose content, cationic Na+, K+, Na+/K+ ratio, and coloration," Breast Cancer Research and Treatment, Vol. 13, pp. 71-78 1989.
i	Petrakis, "Nipple Aspirate Fluid in Epidemiologic Studies of Breast Disease", Epidermiologic Reviews, Vol. 15, No. 1, pp. 188-195 (1993)
	Petrakis, "Physiologic, biochemical, and cytologic aspects of nipple aspirate fluid," Breast Cancer Research and Treatments Vol. 8, pp. 7-9 1986.

EXAMINER

DATE CONSIDERED

MAY 1 4 2002

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. NEOMTRX.4C1DV2

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FILING DATE 02/08/2002

GROUP 1645

TECH CENTER 1600/2900

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	Pitt "Vitamin A" In: Fat soluble vitamins: Their biochemistry and applications, A. Diplock (Ed.), pp. 1-75, London: Heinemann 1985.
	Porter-Jordan et al., Hematol. Oncol. Clin. North Amer. 8: 73-100 1994.
•	Potishman et al., "Breast cancer and dietary and plasma concentrations of carotenoids and vitamin A," American Journal of Clinical Nutrition, Vol. 52, pp. 909-915 1990.
	Rohan et al., "A population based case-control study of diet and breast cancer in Australia American Journal of Epidemiology, Vol. 128, pp.478-489 1988.
5.45 EO	Sarhadi et al., <u>Br J Plast Surg</u> , (8): 668-670, 1997.
LYFIL	Sartorius "Breast fluid cells help in early cancer detection," Journal of the American Medical Association, Vol. 224, pp. 823-827 1973.
OHIGINALLY FILED	Sartorius et al., "Cytologic evaluation of breast fluid in the detection of breast disease," Journal of the National Cancer Institute, Vol. 59, pp. 1073-1078 1977.
5	Sauter, et al.; "Nipple aspirate fluid: a promising non-invasive method to identify cellular markers of breast cancer risk"; British Journal of Cancer (1997) 76(4) pp. 494-501
	Seud et al., J. Reprod Med., 38(6), 438-442,1993.
	Siskind et al., "Breast cancer and breastfeeding: Results form an Australian case-control study," American Journal of Epidemiology, Vol. 130, pp. 229-236 1988.
	Taylor-Papadimitriou et al., "Cell lineage and interactions in neoplastic expression in the human breast," In: <u>Understanding Breast Cancer</u> , M. Rich, J. Hager, & P. Furmanski (Eds.), pp. 215-246, New York: Marcek Dekker, Inc. 1983.
	Van't Veer et al., "Dietary fiber, beta-carotene, and breast cancer: Results from a case-control study," International Journal of Cancer, Vol. 45, pp. 825-828 1990.
	Visozo et al., "Factors affecting protein composition of breast secretions from nonlactating women," <u>Breast Cancer Research</u> , Vol. 23, pp. 251-258 1992.
	Vizoso et al., Relationship Between Serum Prolactin Levels and Protein Composition of Breast Secretions in Nonlactating Women, Journal of Clinical Endocrinology and Metabolism, Vol. 79, No. 2, pp. 525-529, 1994
	Wald et al., "Plasma retinol, beta-carotene, and vitamin E. levels in relation to further risk of breast cancer," British Journal of Cancer, Vol. 49, pp. 321-324 1984.
	Weisberger "Nutritional approach to cancer prevention with emphasis on vitamins, antioxidants, and carotenoids," American Journal of Clinical Nutrition, Vol. 53, pp. 226-237 1991.
	Wrensch et al., "Breast Cancer Incidence in Women with Abnormal Cytology in Nipple Aspirates of Breast Fluid," American Journal of Epidemiology, Vol. 135, No. 2, 1992
	Wrensch et al., "Factors associated with obligating nipple aspirate fluid: Analysis of 1428 women and literature reviews," Breast Cancer Research and Treatment, Vol. 15, pp. 39-51 1990.
	Yoo et al, "Independent protective effect of lactation against breast cancer: A cast-control study in Japan," American Journal of Epidermiology, 135, 725-733, 1992.
	Yuan et al., "Risk factors for breast cancer in Chinese women in Shanghai," Cancer Research, Vol. 48, pp. 1949-1953 1988.

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DATE CONSIDERED

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	FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY, DOCKET NO. NEOMTRX.4C1DV2	APPLICATION NO. 10/072,543
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EXAMINER INITIAL

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

"Final Results of Ductal Lavage Study Presented At 23rd Annual San Antonio Breast Cancer Symposium: Premalignant and Malignant Cells Detected in Women at High-risk for Breast Cancer"; http://www.ductallavage.com/Product/Text/San Antonio release.html

"Lancet Study Shows Promising New Breast Cancer Research Application Using Ductal Lavage"; http://www.ductallavage.com/Product/Text/FINALPDHLancetreleased4.26.01htm

"Study Demonstrates Ductal Lavage Collects Abnormal Breast Cells That Can Help Assess Breast Cancer Risk"; http://www.ductallavage.com/Product/Text/acog.htm; *University Physicians Medical Group*

"Study: Ductal Lavage Shows Promise in Breast Cancer Detection"; IHS® Health Goup Medical Industry Today.htm

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